

REMARKS

Reconsideration is requested.

Claims 12, 13, 21, 29 and 32-38 are pending.

The Section 103 rejection of claims 12, 13, 21, 29 and 32-38 over Petyaev (WO 03/017992) in view of Ruggeri (U.S. Patent No. 6,369, 075), is traversed.

Reconsideration and withdrawal of the rejection are requested in view of the following distinguishing remarks.

The Examiner is understood to rely on Petyaev for a treatment of atherosclerosis by administration of azithromycin and a metal chelator, such as aspirin. The Examiner acknowledges that Petyaev fails to teach a method of reducing apolipoprotein-B (apoB) levels in the vascular system. See page 2 of the Office Action dated February 12, 2009.

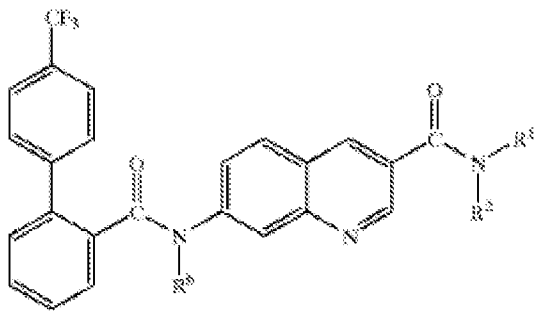
The Examiner relies on Ruggeri to

“disclose that a patient in need of apolipoprotein-B secretion inhibition is a patient having a disease condition in which apolipoprotein-B plays a role in the disease or condition such as patients having or are at risk of having atherosclerosis, hyperlipidemia and hypercholesterol.” Id.

The Examiner concludes from the combination of references that it allegedly would have been obvious to have administered the combination of azithromycin and a metal chelator of Petyaev to patients in need of reduction of apolipoprotein “since such patients having or are at risk of having atherosclerosis are in need of such treatment.” See page 3 of the Office Action dated February 12, 2009.

The applicants note that Petyaev teaches, in part, a treatment of atherosclerosis by administering azithromycin and a metal chelator. The mechanism of the treatment described in Petyaev however is a reduction in lipoprotein peroxidation by administering the combination of azithromycin and a metal chelator. As admitted by the Examiner, there is no disclosure in Petyaev of reducing apoB levels. There is no suggestion in Petyaev of reducing apoB levels by administering azithromycin and a metal chelator.

As noted by the Examiner, Ruggeri describes a inhibition of apoB secretion can be useful to treat atherosclerosis. Ruggeri teaches the use of compounds of the following structure to inhibit the secretion of apoB and thereby treat a number of diseases including atherosclerosis:



Ruggeri also teaches that inhibition of apoB secretion “typically results in the lowering of plasma concentrations of compounds that contain apoB”, such as LDL. See column 1, lines 51-54 and column 1, lines 31-33 of Ruggeri. Ruggeri further teaches that reduction in LDL levels has been used as a surrogate for reduction of apoB levels. See column 3, lines 10-65 of Ruggeri.

One of ordinary skill in the art will understand from Petyaev and Ruggeri that atherosclerosis may be treated by reducing lipid peroxidation (Petyaev) and/or by

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reducing secretion of apoB (Ruggeri). There is no suggestion in the art however that every treatment of atherosclerosis will necessarily involve a reduction in apoB levels, as appears to be the basis of the Examiner's obviousness rejection.

Moreover, the presently claimed invention defines methods whereby apoB levels in the vascular system are reduced without reducing LDL-cholesterol levels. The claimed methods are therefore contrary of Ruggeri which teaches that reduction in apoB secretion would result in a decrease of LDL and other lipoproteins that contain apoB.

The claimed methods are submitted to be patentable over the cited combination of art. Withdrawal of the Section 103 rejection is requested along with a Notice of Allowance. The Examiner is requested to contact the undersigned, preferably by telephone, in the event anything further is required.

Respectfully submitted,

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